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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,867	07/03/2001	Banning G. Lary	SYN-053	4123

7590  
David P. Gordon, Esq.  
65 Woods End Road  
Stamford, CT 06905

11/20/2003

EXAMINER

MENDEZ, MANUEL A

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/898,867

Applicant(s)

LARY ET AL.

Examiner

Manuel Mendez

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3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 35-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-8 and 10-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

**Claims 1, 2, and 20** are rejected under 35 U.S.C. 102(e) as being anticipated by Kokish, et al. The cited patent discloses a first catheter, an inflatable balloon, a second catheter, a self-expanding balloon coupled to the distal end of the second catheter, a third catheter tube; wherein at least one of the second catheter tube and third catheter tubes is adapted to receive and deliver drug to the location of the self expanding balloon.

**Claims 15-19** are rejected under 35 U.S.C. 102(b) as being anticipated by O'Donnell. The cited patent discloses a catheter, a drug reservoir, and dispensing means being adapted to automatically dispense the drug from the reservoir into the lumen of the catheter. In column 4, line 60, the specification clearly states that therapeutic drugs can be substituted for the radiopaque fluid and the inflatable member can have holes to allow the drug diffuse in a controlled manner.

Claims 24 rejected under 35 U.S.C. 102(b) as being anticipated by Zacca, et al. The cited patent discloses a first catheter tube, a self-expanding balloon coupled to the first end of the first catheter tube, and a second catheter tube having a lumen.

Claims 26-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Farley, et al. Farley discloses the steps of delivering a first catheter having a balloon coupled at a distal end thereof through an incision and up the varicose vein, expanding the balloon, and dispensing a sclerosing agent adjacent the balloon.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-8 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kokish, et al., in view of O'Donnell and Hasson. The Kokish, et al. Patent does not disclose locking means or a drug dispenser having a drug reservoir and a drug outlet. However, the use of locking devices to ensure no relative movement between the various tubular bodies of a catheter is conventional according to the teachings of Hasson. The Hasson Patent shows in figure 4, locking element (114). Based on the above evidence, it would have been obvious for a person of ordinary skill in the art, to modify the catheter disclosed by Kokish, et al., with a locking device. Conclusively, such enhancement would have been considered an obvious design choice. Concerning the drug dispenser, O'Donnell demonstrates that the use of drug dispensers in combination with balloon catheters is conventional in the art. Therefore, for a person of ordinary skill in the art, modifying the balloon catheter disclosed by Kokish, et al., with a drug dispensing system having a drug reservoir would have been considered another obvious design alternative.

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kokish, et al., in view of Sheridan and Zacca, et al. The Kokish, et al. Patent does not disclose a balloon made of plastic or wire, and having an abrasive surface. Sheridan

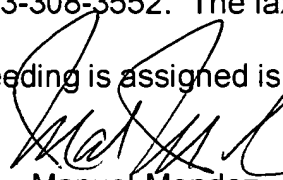
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discloses a balloon made of plastic, and Zacca, et al. discloses a balloon made of wires having an abrasive surface. Accordingly, for a person of ordinary skill in the art the modification of the balloons in Kokish, et al. with balloons made of plastic or wire, and moreover, having an abrasive surface, would have been considered obvious design alternatives.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kokish, et al., in view of Wyszala, et al. The Kokish, et al. Patent discloses a self-expanding balloon having pores. Kokish, et al. does not disclose an abrasive surface on the balloon surface. Wyszala, et al., teaches that expandable balloons having abrasive surfaces are conventional in the art. Accordingly, for a person of ordinary skill in the art, it would have been obvious to modify the balloons of Kokish, et al. with an abrasive surface. Conclusively, the use of abrasive surfaces on balloons would have been considered an obvious design alternative.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3590.



Manuel Mendez  
Primary Examiner  
Art Unit 3763